

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

-----X
UNITED STATES OF AMERICA ex rel. YNKDY-2,
et al.

Plaintiffs,

-against-

SHIEL MEDICAL LABORATORY, et. al.

Defendants.
-----X

:
: Civil Action No. 16-CV-1090-NGG
:

**MEMORANDUM OF LAW
IN SUPPORT OF
DEFENDANTS SHIEL
MEDICAL LABORATORY
AND BIM MEDICAL
INC.'S MOTION TO
DISMISS THIRD
AMENDED COMPLAINT**

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Date of Service: October 30, 2023

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Defendants BIM Medical, Inc. (“**BIM**”) and Shiel Medical Laboratory (“**Shiel Lab**”, and together with BIM collectively, the “**Moving Defendants**”) submit this memorandum of law in support of their motion to dismiss the Third Amended Complaint (“**TAC**”), ECF 65, of Relator YNKDY-2, a California corporation (“**Relator**”), and state as follows:

PRELIMINARY STATEMENT

Seven years ago – in March 2016 – Relator filed this *qui tam* action under seal for itself and on behalf of the United States, the State of New York, and the State of New Jersey, asserting claims under the Federal False Claims Act (the “**FCA**”), 31 U.S.C. § 3729 *et seq.*, the New York State False Claims Act (the “**NYFCA**”), N.Y. Fin. Law § 187 *et seq.*, the New Jersey False Claims Act (the “**NJFCA**”), N.J. Stat. Ann. § 2A:32C-1 *et seq.*, and other laws alleging, *inter alia*, that “Defendants” knowingly submitted claims for reimbursement for laboratory tests that were not reasonable or necessary or that were furnished pursuant to improper referrals and kickbacks. ECF 1.

Shortly after Relator filed its Second Amended Complaint (the “**SAC**”), ECF 22, which added employment retaliation claims under the FCA and the New Jersey Conscientious Employee Protection Act, N.J.S.A. 34:19-1 *et seq.* (“**NJ CEPA**”), BIM, Shiel Lab and defendant Jack Basch filed pre-motion letters (the “**First Pre-Motion Letters**”), ECF 52 and 54, explaining numerous reasons why this Court should dismiss each and every claim in Relator’s SAC. Before a pre-motion conference could be heard regarding the First Pre-Motion Letters, Relator filed the TAC. Remarkably, the TAC does not substantively change anything from the SAC, despite the fact that the First Pre-Motion Letters identified multiple fatal issues with the allegations in the SAC. As explained below, because the TAC is riddled with fatal flaws and Relator has had numerous opportunities to correct those flaws and yet still has not done so, dismissal of the TAC in its entirety with prejudice is not only warranted, but is required as a matter of law.

STATEMENT OF ALLEGATIONS

The original Complaint in this case was filed under seal on March 4, 2016. ECF 1. Relator filed its first Amended Complaint on March 2, 2017, ECF 9 and filed its SAC on February 9, 2022. On June 14, 2022, the federal and state governments unanimously declined to intervene, and the matter was unsealed. ECF 24-28. Relator filed the TAC on May 10, 2023.

Relator is a California corporation with no direct or personal knowledge of the matters in the TAC. *See* TAC ¶ 10. Relator’s principal, “John Doe”, allegedly “held a senior position within Shiel” and dealt with lab testing for skilled nursing facilities since “the mid-1990s’.” *Id.* ¶¶ 10, 103, 167. According to the TAC, “John Doe” allegedly “has direct and personal knowledge of the matters alleged [in the TAC.]” *Id.* The TAC alleges that “Doe” was terminated on February 21, 2017. *Id.* ¶¶ 174, 16(c)-(d).

The TAC specifically names seven defendants, including BIM Medical Inc. and “Shiel Medical Laboratory,” although the TAC’s case caption does not indicate Shiel Lab’s legal identity. The TAC alleges that Shiel Lab, founded in 1962, performs laboratory testing that provides information regarding the diagnosis and treatment of disease. *Id.* ¶¶ 2-3. The TAC alleges that “Defendant Shiel Medical Laboratory was a private corporation incorporated in the State of New York [] with its principal place of business in Brooklyn, New York.” *Id.* ¶¶ 2, 11. Confusingly, while the TAC alleges that “[i]n November 2013 Shiel [Lab] became BIM Medical, Inc.”, the TAC also alleges that “[BIM] is another private corporation ... with the same partners who owned and sold [“Shiel Medical Laboratories” in 2013].” TAC ¶¶ 2, 12 (emphasis added).

On November 20, 2013, a Certificate of Amendment to the Restated Certificate of Incorporation of Shiel Medical Laboratory, **Inc.** (the “**Certificate of Amendment**”) was filed with the New York Department of State Division of Corporations (“**NYDOS-DC**”) changing the entity

name from Shiel Medical Laboratory, **Inc.** to BIM Medical Inc. (the “**Entity Name Change**”). *See* Affidavit of Nicole M. Barnard (“**Barnard Aff.**”), a true and correct copy of which is attached hereto as **Exhibit 1**, at ¶ 4 and Ex. A. The Entity Name Change occurred around the same time when Spectra Holdco, LLC (“**Spectra**”) purchased the assets of Shiel Medical Laboratory, **Inc.** (the “**Asset Sale**”) from Shiel Medical Laboratory, **Inc.** *See* Ex. 1, Barnard Aff., at ¶ 5; *see also* ECF 72; TAC ¶¶ 2, 11, 16-17, 166. After the Asset Sale, BIM filed a “Certificate of Assumed Name” with the NYDOS-DC (the “**Certificate of Assumed Name**”) and assumed the trade name of “Shiel Medical Laboratory”. *See* Ex. 1, Barnard Aff., at ¶ 6 and Ex. B. Notably, the TAC is devoid of any allegations specific to BIM other than the aforementioned party allegations in paragraphs 2 and 12 of the TAC.

The TAC also alleges that Shiel Lab was purchased in 1994 by three individuals, including Defendant Jack Basch, and that Shiel Lab was purchased again in 2013 by Fresenius Medical Care of North America (“**Fresenius**”) and Fresenius Medical Care Holdings, Inc. (“**Fresenius Holdings**”). TAC ¶¶ 2, 11, 16(a).¹ The TAC alleges that since the Asset Sale in 2013, “the laboratory business has been operated by Spectra Laboratories, in Rockleigh, New Jersey.” *Id.* ¶ 166. According to the TAC, Defendants Fresenius Holdings, Spectra Holdco, LLC (“**Spectra**”) and Shiel Lab are related and are part of the “Fresenius network,” *id.* ¶ 17(a), and Defendants Fresenius, Fresenius Holdings, Shiel Holdings, LLC are all alleged to have a business address in Waltham, Massachusetts, *id.* ¶¶ 13, 14, 17(a).

According to the TAC, “Defendants” allegedly billed for lab tests that were not “reasonable and necessary” because (a) “Shiel” representatives allegedly inserted diagnosis codes that should have been supplied by a doctor to satisfy documentation requirements, and (b) in 2004, one

¹ Relator’s reference to Shiel Lab here is erroneous. The reference to Shiel Medical Laboratory should be to Shiel Medical Laboratory, **Inc.** *See* TAC ¶ 11.

employee allegedly had “expensive” tests added to lab orders. *See id.* ¶¶ 77, 81-95. The TAC provides no other examples or details. The TAC also alleges, however, that doctors ordered the tests. *Id.* ¶¶ 5, 87, 93. Notably, the TAC does not allege that any diagnosis code was inaccurate for any patient. *See* TAC, generally. In regard to knowledge of the alleged “falsification of ICD-9 and ICD-10 codes”, the TAC does not allege that BIM or Shiel Lab knew of the alleged falsification. *See* TAC, generally. Rather, the TAC alleges that the alleged code falsification “was known by Fresenius Laboratories’ Chief Operating Officer and the vice-president of Billing and Contracting,” TAC ¶ 91, or that “Defendants” collectively knew, *see id.* ¶¶ 128-129, 131-134, 146, 158. The TAC does not identify any specific claim containing one of the alleged code falsifications that was submitted to the government or any false claim that was paid by the government. *See* TAC, generally.

Further, the TAC alleges that “Defendants” allegedly paid kickbacks to doctors, such as “free advertising,” electronics, gifts, parties, meals, and phlebotomist services, and gave “discounts” to nursing homes. *Id.* ¶¶ 78-79, 96-118. Again, the TAC provides few facts other than alleging the involvement of various nursing homes, some of which allegations are made upon “information and belief.” *See id.* ¶¶ 78-79, 96-118. Notably, the TAC does not identify any impact on lab orders or claims to the government. *See* TAC, generally. In regard to knowledge, the TAC does not allege that BIM or Shiel Lab knew of the alleged financial inducements. *See* TAC, generally. Rather, the TAC alleges merely that “Defendants” collectively knew. *See* TAC ¶¶ 97-121, 128-129, 131-134, 146, 158. Once again, the TAC also does not identify any specific false claim that was submitted to the government or any false claim that was paid by the government. *See* TAC, generally.

The TAC also alleges that “Defendants” should have conducted “audits” to identify “overpayment refunds due Medicare because [of] each of the previously enumerated false billing

schemes.” TAC ¶ 137. The TAC does not, however, identify a single example of any such overpayment. *See* TAC, generally.

In regard to timing, the TAC alleges generally that Defendants’ alleged conduct and submission of “false claims” has occurred “since 1996,” TAC ¶¶ 4, 103, but the TAC is practically devoid of dates identifying when the alleged conduct occurred, *see* TAC, generally. In the few places where the TAC attempts to include a date regarding its allegations, the TAC alleges that the conduct occurred in 2014, which is after the Asset Sale when Fresenius/Spectra acquired the assets of Shiel Medical Laboratory, **Inc.** *Id.* ¶¶ 87, 92.

Despite the highly generalized allegations, Relator brings the following seven causes of action in the TAC: (1) Count I is a claim brought under §§ 3729 (a)(1) and (a)(1)(A) of the FCA for presentation of false claims; (2) Count II is a claim brought under § 3729(a)(1)(B) of the FCA for false statements material to false claims; (3) Count III is a FCA “reverse” false claim for failure to return overpayments; (4) Count IV is a claim brought under the NYFCA for presentation of false claims, false statements material to false claims and failure to return overpayments; (5) Count V is a claim brought under the NJFCA for presentation of false claims, false statements material to false claims and failure to return overpayments; (6) Count VI is a claim brought under the FCA by Relator on behalf of non-party “John Doe” for illegal retaliation; and (7) Count VII is a claim brought under the NJ CEPA by Relator on behalf of non-party “John Doe” for illegal retaliation.

ARGUMENT

As an initial matter, the TAC should be dismissed in its entirety against all Defendants under Federal Rule of Civil Procedure² 10(a) and supporting case law because Relator – a shell corporation formed for the purpose of hiding the identity of non-party “John Doe” – is not a proper

² “Rule” is used herein to reference a Federal Rule of Civil Procedure, unless otherwise stated.

party. Additionally, the TAC should be dismissed in its entirety as against Shiel Medical Laboratory (no “**Inc.**”) for lack of jurisdiction because Shiel Lab is nothing more than a trade name for BIM. Large portions of Counts I – V of the TAC also should be dismissed on limitations grounds or as inapplicable to BIM or its predecessor. Furthermore, the Federal and State fraud and fraud-based claims in Counts I–V of the TAC should be dismissed in their entirety because Counts I-V are (i) not pled with the requisite particularity under Rule 9(b) and (ii) not sufficiently or plausibly pled under Rule 12(b)(6). The employment retaliation claims in Counts VI and VII likewise should be dismissed for lack of jurisdiction because Relator lacks standing and, as against BIM and Shiel Lab, should be dismissed under Rule 12(b)(6) because, *inter alia*, the TAC fails to, and in fact cannot, allege that either BIM or Shiel Lab was the employer of “John Doe” at the time of the alleged retaliatory termination. Lastly, any request by Relator for further amendment should be denied as futile, unjust and unwarranted.

I. LEGAL STANDARDS

A. Fed. R. Civ. P. 12(b)(1)

“Fed. R. Civ. P. 12(b)(1) provides for dismissal when a federal court lacks jurisdiction over the subject matter of a claim.” *City of New York v. Milhelm Attea & Bros., Inc.*, 550 F.Supp.2d 332, 339 (E.D.N.Y. 2008). In considering a motion to dismiss under Fed. R. Civ. P. 12(b)(1), a court must take all facts alleged in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Id.* at 340 (citing *Raila v. United States*, 355 F.3d 118, 119 (2d Cir.2004)). In resolving such a motion, a district court may, however, refer to evidence outside the pleadings. *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). The plaintiff, as the party asserting federal jurisdiction, bears the burden of proving “by a preponderance of the evidence” that subject matter jurisdiction exists. *Platinum-Montaur Life Scis., LLC v. Navidea Biopharmaceuticals, Inc.*, 943 F.3d 613, 617 (2d Cir. 2019).

“As standing is a limitation on the authority of a federal court to exercise jurisdiction, it is properly addressed within the context of a Rule 12(b)(1) motion.” *Milhelm Attea & Bros., Inc.*, 550 F.Supp.2d at 340 (internal quotation marks and citation omitted). If a plaintiff lacks standing to maintain its claim, the claim is not justiciable and must be dismissed for lack of subject matter jurisdiction. *Trump v. New York*, 141 S. Ct. 530, 535 (2020) (per curiam); *see also Cent. States Se. & Sw. Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C.*, 433 F.3d 181, 198 (2d Cir. 2005) (“If plaintiffs lack Article III standing, a court has no subject matter jurisdiction to hear their claim.”).

B. Fed. R. Civ. P. 12(b)(2)

In deciding a motion to dismiss for lack of personal jurisdiction, a court “has considerable procedural leeway” and “may determine the motion on the basis of affidavits alone; or it may permit discovery in aid of the motion; or it may conduct an evidentiary hearing on the merits of the motion.” *McConney v. Amtrak*, No. 18CV05290-(NGG) (RER), 2020 WL 435366, at *2 (E.D.N.Y. Jan. 28, 2020) (quoting *Dorchester Fin. Sec., Inc. v. Banco BRJ, S.A.*, 722 F.3d 81, 84 (2d Cir. 2013) (summary order)). “Where the court opts not to hold a hearing or order jurisdictional discovery, the plaintiff need only make a *prima facie* showing of jurisdiction.” *Id.* (citing *Dorchester Fin. Sec., Inc.*, 722 F.3d at 84). “A *prima facie* case requires non-conclusory fact-specific allegations or evidence showing that activity that constitutes the basis of jurisdiction has taken place.” *Id.* (quoting *Chirag v. MT Marida Marguerite Schiffahrts*, 604 F. App’x 16, 19 (2d Cir. 2015) (summary order)); *see also DeLorenzo v. Viceroy Hotel Grp., LLC*, 757 F. App’x 6, 8 (2d Cir. 2018) (“[C]onclusory non-fact-specific jurisdictional allegations or legal conclusion[s] couched as a factual allegation will not establish a *prima facie* showing of jurisdiction.” (alterations in *DeLorenzo*) (internal quotation marks and citation omitted)).

C. Fed. R. Civ. P. 9(b)

Complaints alleging violations of the FCA must meet the heightened pleading standard imposed by Rule 9(b). *See Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476–77 (2d Cir.1995) (citing cases). “The purpose of Rule 9(b) is threefold—it is designed to provide a defendant with fair notice of a plaintiff’s claim, to safeguard a defendant’s reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit.” *O’Brien v. Nat’l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991). Rule 9(b)’s particularity standard is “rigorously enforced” in the Second Circuit. *United States ex rel. Gelbman v. City of New York*, 790 F. App’x 244, 247 (2d Cir. 2019) (summary order) (citation omitted).

D. Fed. R. Civ. P. 12(b)(6)

To survive a motion to dismiss under Rule 12(b)(6), a complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim will only have “facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The plaintiff must allege sufficient facts to show “more than a sheer possibility that a defendant has acted unlawfully.” *Id.* A complaint is properly dismissed where, as a matter of law, “the allegations in a complaint, however true, could not raise a claim of entitlement to relief.” *Twombly*, 550 U.S. at 558. Although the court must accept as true all well-pled factual allegations in the complaint and draw all reasonable inferences in the plaintiff’s favor, *Steginsky v. Xcelera Inc.*, 741 F.3d 365, 368 (2d Cir. 2014), that principle “is inapplicable to legal conclusions,” and the court need not credit “mere conclusory statements” or “threadbare recitals of the elements of a cause of action,” *Iqbal*, 556 U.S. at 678.

II. THE COURT SHOULD DISMISS THE TAC IN ITS ENTIRETY BECAUSE RELATOR IS NOT A PROPER PARTY UNDER FED. R. CIV. P. 10(a).

In the present action, Relator is a corporate shell known as “YNKDY-2” that exists for the

sole purpose of asserting the claims of an unnamed individual (the “**Anonymous Individual**”), also known as “John Doe”,³ who is Relator’s principal and is alleged to have “held a senior position with Shiel” with “direct and personal knowledge of the matters alleged.” TAC ¶¶ 10, 165-181. The TAC’s use of a shell corporation as the Relator in a *qui tam* action in order to provide anonymity to the Anonymous Individual (aka John Doe) contravenes Rule 10(a) and the presumption of openness in judicial proceedings, and prejudices Defendants.

As a general rule, a plaintiff (or relator) cannot file or maintain complaints anonymously or under a pseudonym. To be sure, Rule 10(a) provides that “[t]he title of the complaint must name all the parties.” Fed. R. Civ. P. 10(a). Similarly, the presumption of openness in judicial proceedings requires that the parties to a lawsuit be identified. *See, e.g., Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589, 597 (1978). This vital presumption enables “public scrutiny of judicial proceedings” and is necessary for the simple reason that the public has the “right to know who is using their courts.” *Sealed Plaintiff v. Sealed Defendant*, 537 F.3d 185, 188-89 (2d Cir. 2008) (citation omitted). Where, as here, a judicial proceeding involves “matters of particular concern to the public, such as allegations of fraud against the government” the presumption of openness “is especially strong”. *U.S. ex rel. Permison v. Superlative Techs., Inc.*, 492 F. Supp. 2d 561, 564 (E.D. Va. 2007). In very limited circumstances, courts may allow a plaintiff to file or maintain an action under a pseudonym for purposes of anonymity if “the plaintiff’s interest in anonymity” outweighs “both the public interest in disclosure and any prejudice to the defendant.” *Sealed Plaintiff*, 537 F.3d at 189. This balancing inquiry requires a court to consider factors such as whether the matter is “highly sensitive and [of a] personal nature,” “whether identification poses a risk of retaliatory physical or mental harm,” and “whether the defendant is prejudiced by allowing

³ *See* <https://bizfileonline.sos.ca.gov/search/business>. YNKDY-2 was first filed as a California corporation on February 2, 2016. The original Complaint was filed on March 4, 2016.

the plaintiff to press his claims anonymously[.]” *Id.* at 190 (internal citations omitted) (providing a non-exhaustive list of factors). With these factors in mind, courts have repeatedly rejected efforts by relators to remain anonymous, particularly where the risk of harm is based on concerns of employer retaliation or industry-wide blacklisting or retaliation. *See, e.g., U.S. ex rel. Doe v. Horizon Therapeutics PLC*, No. 20-CV-3207-MKV, 2021 WL 3500911, at *1 (S.D.N.Y. Aug. 9, 2021) (explaining that “concerns of industry-wide retaliation are wholly conjectural and have been repeatedly rejected by courts” (citing cases)); *U.S. v. UCB, Inc.*, No. 14-CV-2218 (TPG), 2017 WL 838198, at *2 (S.D.N.Y. Mar. 3, 2017) (hereinafter “*UCB, Inc.*”) (“Courts generally do not find that the risk of employer retaliation outweighs the presumption of public access to documents filed in FCA actions.” (collecting cases)); *U.S. ex rel. Wenzel v. Pfizer, Inc.*, 881 F. Supp. 2d 217, 222 (D. Mass. 2012) (refusing to seal *qui tam* complaint despite relator’s claim that he would face blacklisting by healthcare industry).

Here, Relator is a corporate shell known as “YNKDY-2” that exists for the sole purpose of asserting the claims of the Anonymous Individual who is Relator’s principal and is alleged to have “held a senior position with Shiel” with “direct and personal knowledge of the matters alleged.” TAC ¶¶ 10, 165-181. Even if the Anonymous Individual belatedly sought leave of court to proceed anonymously, none of the Second Circuit’s factors tilt in favor of allowing the Anonymous Individual to hide behind a corporate shell to conceal his identity. **First**, because the present matter is a *qui tam* case alleging fraud against federal and state governments, the public interest in openness and disclosure is especially high. *See Permison*, 492 F. Supp. 2d at 564. **Second**, Defendants are unquestionably prejudiced by the Anonymous Individual’s anonymity because it hinders Defendants’ ability to meaningfully respond to the TAC’s allegations. **Third**, this case does not involve anything highly sensitive or personal, and there is nothing indicating any risk of retaliatory physical or mental harm. *See* TAC, generally. **Fourth**, the TAC’s sole attempt to justify

anonymity, *see* TAC ¶ 167, is based on alleged employment-related concerns that courts consistently find insufficient to justify anonymity in FCA actions. *See, e.g., UCB, Inc.*, 2017 WL 838198, at *2, *supra*; *Wenzel*, 881 F. Supp. 2d at 222, *supra*. The balancing inquiry weighs heavily, if not completely, against allowing anonymity in this action.

Significantly, this same issue existed in the SAC and was highlighted in the First Pre-Motion Letters. Nonetheless, in the TAC, the Anonymous Individual continues to refuse to identify himself and, instead, continues to improperly hide his identity behind the corporate shell “YNKDY-2”. These actions violate Rule 10(a) and the presumption of openness in judicial proceedings. Thus, this action cannot proceed. *See Publicola v. Lomenzo*, 54 F.4th 108, 114 (2d Cir. 2022) (finding that the plaintiff’s failure to comply with requirements to disclose his identity justified dismissal of the action).

III. THE COURT SHOULD DISMISS “SHIEL MEDICAL LABORATORY” AND ALL CLAIMS AGAINST IT FOR LACK OF JURISDICTION UNDER FED. R. CIV. P. 12(b)(1) AND FED. R. CIV. P. 12(b)(2).

In Counts I–VII of the TAC, Relator seeks judgment against, *inter alia*, Shiel Lab. Relator, however, fails to, and cannot, meet its burden of showing that subject matter jurisdiction or personal jurisdiction exist in the first instance. A party to an action must have the capacity to be sued. *Ragin v. Harry Macklowe Real Est. Co.*, 126 F.R.D. 475, 480 (S.D.N.Y. 1989). “[E]xistence in law must be alleged in [a] pleading[.]” *Id.* (citing *Little Shoppe Around the Corner v. Carl*, 363 N.Y.S.2d 784 (Rockland Cty. Ct. 1975)). To have the capacity to be sued, a party must be a “natural person, a corporation, a partnership, or any other legally cognizable entity.” *Id.* Where a party does not have the legal capacity to be sued, any action brought against it is a nullity and cannot be maintained. *See id.* (“[N]o action can be maintained against a nullity.”). “It is well settled that a trade name ‘has no separate jural existence, and that it can neither sue nor be sued independently of its owner,’” *See, e.g., Leser v. Karenkooper.com*, 856 N.Y.S.2d 498 (N.Y. Cty.

Sup. Ct. 2008) (citation omitted). Thus, an action brought against a trade name is a non-justiciable nullity. *See Thompson v. Jamaica Hosp. Med. Ctr.*, No. 13 CIV. 1896-RWS, 2016 WL 4556905, at *5 (S.D.N.Y. Aug. 30, 2016) (noting trade names are not proper parties).

Here, Relator fails to, and cannot, sufficiently allege that Shiel Lab has the capacity to be sued. In the case caption, the TAC identifies “Shiel Medical Laboratory” as a defendant but fails to indicate in the caption whether Shiel Lab is a legal entity in the first instance, much less indicate the type of alleged legal entity. The reason for Relator’s failure is simple: Relator knows that Shiel Lab is not a legal entity. To be sure, although the TAC alleges that “Defendant Shiel Medical Laboratory was a private corporation incorporated in the State of New York [] with its principal place of business in Brooklyn, New York,” TAC ¶ 11 (emphasis added); *see also id.* ¶ 2, the TAC also concedes that Shiel Lab is the same entity as BIM, which is already named as a defendant in this case. *See* TAC ¶ 2 (alleging that “[i]n November 2013 Shiel became BIM Medical, Inc.” (emphasis added)).

Corporate records obtainable from the NYDOS-DC, which this Court can judicially notice because they are publicly accessible⁴ and their accuracy cannot reasonably be questioned, *see Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016); FED.R.EVID. 201(b), determinatively show that Shiel Lab is not a corporation or legal entity capable of being sued. *See* Ex. 1, Barnard Aff., at ¶¶ 4-6 and Exs. A & B. Specifically, NYDOS-DC records reveal that on November 20, 2013, the Certificate of Amendment was filed with the NYDOS-DC for purposes of the Entity Name Change, which changed the entity name of Shiel Medical Laboratory, **Inc.** to BIM Medical Inc. *See* Ex. 1, Barnard Aff., at Ex.A. The Entity Name Change occurred around the same time as the Asset Sale when Spectra (Fresenius) purchased the assets of Shiel Medical

⁴ An entity search for corporate records can be performed via <https://apps.dos.ny.gov/publicInquiry/>.

Laboratory, **Inc.** from Shiel Medical Laboratory, **Inc.** See Ex. 1, Barnard Aff., at ¶ 5; *see also* ECF No. 72; TAC ¶¶ 2, 11, 16-17, 166. After the Asset Sale, BIM filed the Certificate of Assumed Name with the NYDOS-DC and assumed the trade name of “Shiel Medical Laboratory”. See Ex. 1, Barnard Aff., at ¶ 6 and Ex. B.

To the extent Relator intended to sue Shiel Medical Laboratory, **Inc.** prior to the Asset Sale to Spectra/Fresenius, Relator has done so by suing Defendant BIM.⁵ See Ex. 1, Barnard Aff. ¶¶ 4-6. To the extent Relator intended to sue Shiel Medical Laboratory, **Inc.** after the Asset Sale to Spectra/Fresenius, Relator has done so by suing Defendants Spectra and Fresenius. Relator cannot maintain separate claims against “Shiel Medical Laboratory” because Shiel Lab is not a legal entity and has no separate jural existence, making any such claim a non-justiciable nullity. *See, e.g., Ragin*, 126 F.R.D. at 480, *supra*; *Thompson*, 2016 WL 4556905, at *5–6, *supra*. Accordingly, pursuant to Rule 12(b)(2), this Court must dismiss all claims against Shiel Lab for lack of personal jurisdiction. *See, e.g., M.E. Aslett Corp. v. Crosfield Elecs., Inc.*, No. 86 CIV. 3549-CSH, 1987 WL 7023, at *1 (S.D.N.Y. Feb. 17, 1987) (explaining an action against a trade name is subject to dismissal for lack of personal jurisdiction because the trade name defendant “has no independent legal existence and [] lacks the capacity to be sued under New York law[.]”).

Furthermore, because Shiel Lab is not a legal entity and has no separate jural existence, this Court also does not have subject matter jurisdiction over the claims against Shiel Lab. The False Claims Act “subjects to liability ‘[a]ny person’ who, *inter alia*, ‘knowingly presents, or causes to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval.’” *Vermont Agency of Nat. Res. v. U.S. ex rel. Stevens*,

⁵ Relator concedes that Shiel Medical Laboratory, **Inc.** became BIM in November 2013. TAC ¶ 2. Significantly, however, the TAC does not contain any allegations regarding conduct specifically by BIM. See TAC, generally. Thus, it is assumed that Relator sued BIM solely for conduct by Shiel Medical Laboratory, **Inc.** prior to the Asset Sale and the Entity Name Change.

529 U.S. 765, 780 (2000) (alteration in original) (emphasis added) (quoting 31 U.S.C. § 3729(a)). The term “person” does not include a non-legal entity such as a trade name. *Cf. id.* (citing 1 U.S.C. § 1A). Thus, this Court also does not have subject matter jurisdiction over the alleged claims against Shiel Lab, and those claims must also be dismissed pursuant to Rule 12(b)(1).

IV. THE COURT SHOULD DISMISS LARGE PORTIONS OF COUNTS I–V AS TIME-BARRED OR AS INAPPLICABLE TO BIM MEDICAL INC. OR ITS PREDECESSOR, SHIEL MEDICAL LABORATORY, INC.⁶

On the face of the TAC, a large portion of Relator’s claims are barred by limitations. The statute of limitations for claims brought under the FCA and NJFCA is six (6) years. *See* 31 U.S.C. § 3731(b)(1) (6 years); N.J. Stat. § 2A:32C-11(a) (6 years). Limitations under the NYFCA is ten (10) years. *See* N.Y. State Fin. Law § 192(1) (10 years). Here, Relator initially filed the above-captioned case on March 4, 2016. ECF 1. Thus, any claims against Defendants brought under the FCA or NJFCA for conduct that occurred before March 2010 and any claims against Defendants brought under the NYFCA for conduct that occurred before March 2006 are time-barred as a matter of law and must be dismissed. *See* 31 U.S.C. § 3731(b)(1); N.J. Stat. § 2A:32C-11(a); N.Y. State Fin. Law § 192(1). Moreover, given that Spectra/Fresenius purchased the assets of Shiel Medical Laboratory, **Inc.** in 2013, TAC ¶¶ 2, 11, 16(a), any claims involving conduct of Shiel Medical Laboratory, **Inc.** that occurred after the 2013 sale are not applicable to Defendant BIM (or Shiel Medical Laboratory, **Inc.** prior to the Asset Sale). Accordingly, as a matter of law, these claims must be dismissed against BIM (aka Shiel Medical Laboratory, **Inc.** prior to the Asset Sale) and Shiel Lab (if not dismissed for lack of jurisdiction) as time barred.

Furthermore, nearly all of Relator’s claims that rely on allegations of wrongdoing based on

⁶ While Defendants are confident that the Court will dismiss this action and/or the claims against Defendants on jurisdictional grounds, out of an abundance of caution, Defendants make additional non-jurisdictional arguments in the alternative on behalf of Shiel Lab and BIM.

alleged nursing home “discounts” that purportedly began in the “mid-1990’s”, *see* TAC ¶¶ 6, 48-51, 790, 99–118 (the “**Nursing Home Discount Allegations**”), must be dismissed against BIM and Shiel Lab as untimely. Relator filed its original Complaint on March 4, 2016. ECF 1. **Relator did not allege anything regarding wrongdoing based on the Nursing Home Discount Allegations until it filed the SAC on February 9, 2022.** *Compare* Compl., ECF 1 and First Amended Complaint, ECF 9, *with* SAC, ECF 22 ¶¶ 6, 48-51, 79, 99-118. Thus, given the six-year limitations period of the FCA and NJFCA, *see* 31 U.S.C. § 3731(b)(1) and N.J. Stat. § 2A:32C-11(a), any claim in the TAC that (i) is brought under the FCA or NJFCA, (ii) is based on the Nursing Home Discount Allegations and (iii) is alleged to have occurred **on or before February 9, 2016** is time-barred unless such claim relates back to the original Complaint. *See Hayes v. Dep’t of Educ. of City of New York*, 20 F. Supp. 3d 438, 447–48 (S.D.N.Y. 2014) (explaining that where limitations has passed, allegations in an amended pleading are time-barred unless those allegations relate back to the original complaint). Similarly, given the ten-year limitations period of the NYFCA, *see* N.Y. State Fin. Law § 192(1), any claim in the TAC that (i) is brought under the NYFCA, (ii) is based on the Nursing Home Discount Allegations and (iii) is alleged to have occurred **on or before February 9, 2012** is time-barred unless such claim relates back to the original Complaint. *See id.* Here, no claim based on the Nursing Home Discount Allegations relates back to the original Complaint.

Under Rule 15(c), “[a]n amendment to a pleading relates back to the date of the original pleading when” the claim in the amendment “arose out of the conduct, transaction, or occurrence set out ... in the original pleading.” Fed. R. Civ. P. 15(c)(1)(B). In determining relation back, “the central inquiry is whether adequate notice of the matters raised in the amended pleading has been given to the opposing party within the statute of limitations by the general fact situation alleged in the original pleading.... Where the amended complaint does not allege a new claim but renders

prior allegations more definite and precise, relation back occurs.” *United States ex rel. Raffington v. Bon Secours Health Sys., Inc.*, 567 F. Supp. 3d 429, 444 (S.D.N.Y. 2021) (quoting *Slayton v. Am. Exp. Co.*, 460 F.3d 215, 228 (2d Cir. 2006) (punctuation omitted)). In the present case, the Nursing Home Discount Allegations first appearing in the SAC are “new allegations of a completely different character [that arise] from a completely different ‘fact situation’ from what had previously been alleged.” *See id.* Relator tacitly concedes as much. *See* SAC ¶103 (attempting to explain Relator’s failure to include any Nursing Home Discount Allegations in the Complaint and the First Amended Complaint); TAC ¶103 (same). Thus, as a matter of law, claims in the TAC based on the Nursing Home Discount Allegations do **not** relate back under Rule 15(c). *See Hayes*, 20 F. Supp. 3d at 447–48; *Raffington*, 567 F. Supp. 3d at 444. Therefore, as a matter of law, claims brought under the FCA or NJFCA and based on the Nursing Home Discount Allegations that are alleged to have occurred **on or before February 9, 2016** are time-barred, and claims brought under the NYFCA and based on the Nursing Home Discount Allegations that are alleged to have occurred **on or before February 9, 2012** are likewise time-barred. *See Hayes*, 20 F. Supp. 3d at 447–48; *Raffington*, 567 F. Supp. 3d at 444.

Accordingly, as a matter of law, given that Spectra/Fresenius purchased the assets of Shiel Medical Laboratory, **Inc. in 2013**, TAC ¶¶ 2, 11, 16(a): (i) all of Relator’s claims against BIM and Shiel Lab brought under the FCA and NJFCA that are based on the Nursing Home Discount Allegations are time-barred and must be dismissed; and (ii) all of Relator’s claims against BIM and Shiel Lab brought under the NYFCA that are based on the Nursing Home Discount Allegations are time-barred and must be dismissed, except to the extent that Relator has sufficiently alleged such claim between February 9, 2012 and the date in 2013 when Spectra/Fresenius purchased the assets of Shiel Medical Laboratory, **Inc.** (which Relator has not).

V. THE COURT SHOULD DISMISS COUNTS I–V BECAUSE THE ALLEGATIONS FAIL TO SATISFY THE REQUIREMENTS OF FED. R. CIV. P. 9(b) AND FED. R. CIV. P. 12(b)(6).

Claims alleging fraud, including those in Counts I–V of the TAC brought under the FCA and its state-based analogues, “fall within the express scope of Rule 9(b)” and, thus, are subject to its heightened pleading standard. *See Gold*, 68 F.3d at 1476–77; *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04-CV-0704 (ERK), 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (“Rule 9(b) ... also applies to *qui tam* actions under state statutes similar to the FCA.” (citations omitted)). To plead with particularity under Rule 9(b), which is rigorously enforced in the Second Circuit, a plaintiff is required to “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Gelbman*, 790 F. App’x at 247. In other words, “a plaintiff [must] set forth the who, what, when, where and how of the alleged fraud.” *Polansky*, 2009 WL 1456582 at *4 (citation omitted). Under Rule 12(b)(6), a complaint also must plausibly state each claim and must allege sufficient facts in order to do so. *See Ashcroft*, 556 U.S. at 678 (2009). Therefore, to avoid dismissal of Counts I–V under Rules 9(b) and 12(b)(6), the TAC must, *inter alia*: (i) allege fraud or a fraudulent scheme and the submission of false claims with particularity, and (ii) allege facts that plausibly state each claim. *E.g.*, *U.S. ex rel. Moore v. GlaxoSmithKline, LLC*, No. 06 CIV. 6047 BMC, 2013 WL 6085125, at *4 (E.D.N.Y. Oct. 18, 2013). The TAC fails under both standards.

A. Counts I–V fail to satisfy Rule 9(b).

First, the TAC fails to sufficiently allege fraud or a fraudulent scheme against BIM, Shiel Lab or any other Defendant. The vast majority of the TAC’s purported factual allegations are improperly group pled, *see, e.g.*, TAC ¶¶ 77– 81, 88, 90, 96, 119–120, 122–125, 128, 131–133, 136–138, 143–146, 148–151, 156–158, 160, 161–163, 168–169, making it nearly impossible for any

Defendant to know which claims are being alleged against it. Further, the TAC is unclear as to the meaning of the undefined term “Shiel”, which is used throughout the TAC for several different entities. *See, e.g.*, TAC ¶¶ 2-4, 6, 11-12, 13, 6, 49-50, 81-87, 92, 96-104, 106-109, 115-118, 121, 136, 166-167. As a matter of law, Relator’s failure to allege fraudulent conduct specific to BIM, Shiel Lab or any other Defendant does not satisfy Rule 9(b)’s particularity requirement. *See Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993) (“Rule 9(b) is not satisfied where the complaint vaguely attributes the alleged fraudulent statements to ‘defendants.’”).

Further, the TAC does not particularly allege the date or dates when the alleged fraudulent acts or statements occurred. *See* TAC ¶¶ 77-164. In fact, the TAC is practically devoid of dates, making it a complete guessing game for BIM (Shiel Lab or any other Defendant) to try to figure out who the allegations are against, particularly in light of the fact that Shiel Medical Laboratory, **Inc.**, whose conduct is at issue, was owned by different Defendants at different times. *See id.* Two of the few allegations that include a date vaguely allege that “Shiel” submitted false claims “[s]ince at least 1996,” TAC ¶ 4, and that certain alleged inducements “dated back to the mid-1990’s,” TAC ¶ 103. A viable claim for fraud cannot rely on group pleading over such a broad time span, particularly where, as here, ownership of the entity accused of wrongdoing changed. *See Mills*, 12 F.3d at 1175.

Second, despite the fact that “the submission of a false claim is the *sine qua non* of a False Claims Act violation,” *U.S. ex rel. Kester v. Novartis Pharms. Corp.*, 23 F. Supp. 3d 242, 253 (S.D.N.Y. 2014) (internal quotation marks and citation omitted), the TAC fails to sufficiently allege that BIM (or Shiel Lab) submitted any false claims. In fact, the TAC does not allege details regarding any actual false claims or the submission of any actual false claims by any Defendant, much less payment of any actual false claims. *See* TAC ¶¶ 77-164. Because the TAC does not particularly allege “who” did what, when, its allegations of fraud are patently insufficient under

Rule 9(b) and dismissal of Counts I-V is required for that reason alone. *See e.g., Gelbman*, 790 F. App'x at 248–49 (affirming the district court's dismissal for failure to satisfy Rule 9(b)).

B. Counts I–V fail to satisfy Rule 12(b)(6).

First, Relator's claims that Defendants submitted claims for tests "that were not reasonable and necessary" and that it "made, used, and caused to be made or used" false statements to get false claims paid are insufficiently pled as a matter of law. For example, Relator's allegations that in 2004 and 2014 one employee added tests to lab orders that were unnecessary, TAC ¶¶ 92-93, are conclusory and fail to provide substantiating facts to **plausibly** support the assertion. In fact, Relator's allegations that doctors, or doctors' employees or practices, ordered these tests contradict the assertion that tests were unnecessary. *See* TAC ¶¶ 5, 87, 93. The TAC is also devoid of allegations or facts that any codes allegedly "inserted" by "Shiel" employees were inaccurate based on any patient's reported symptoms nor does it consider the making of accurate code edits for tests based on an employee's follow-up of test orders. *See* TAC ¶¶ 77-164. To be sure, following up on orders and making such edits is not improper given that clinical laboratories are required to ensure that there is sufficient documentation in the patient's medical record to establish medical reasonableness and necessity of tests. *See* TAC ¶¶ 31, 60-63. Accordingly, the TAC's allegations that tests were not reasonable and necessary and that false statements were made or used are purely speculative and "cannot plausibly suggest actionable wrongdoing" because they can be explained by lawful behavior. *See Flanagan v. Bahal*, No. 12-2216 (NLH/JS), 2015 WL 9450826, at *5 (D.N.J. Dec. 22, 2015) (finding, *inter alia*, that the relator failed to sufficiently allege that the defendant billed Medicare for medically unnecessary services because there were no allegations as to why, based on patient records, the alleged tests were medically unnecessary). Thus, Relator's claims regarding such tests and statements merely allege a potential opportunity for fraud, which is plainly insufficient to state a claim. *See id.*

Second, Relator's claims based on alleged violations of the federal Physician Self-Referral Law, 42 U.S.C. § 1395nn (the "**Stark Law**") should likewise be dismissed because the TAC fails to allege requisite facts. The Stark Law, which governs physician self-referrals, "prohibits physicians from referring their Medicare and Medicaid patients to business entities in which the physicians or their immediate family members have a financial interest." *U.S. ex rel. Corp. Compliance Assocs. v. N.Y. Soc. for Relief*, No. 07 CIV. 292 PKC, 2014 WL 3905742, at *10 (S.D.N.Y. Aug. 7, 2014) (internal quotation marks and citation omitted). The TAC, however, fails to identify **any** referrals that resulted from any alleged violation of the Stark Law. The TAC is devoid of any factual allegations identifying any physician (or a physician's immediate family member) who had a financial interest in any business entity in the first instance. Without these allegations, there is no basis for a claim under the Stark Law. Thus, the TAC's allegation that "Defendants knowingly compensated physicians and skilled nursing facilities in exchange for referrals, in violation of the Stark Law," TAC ¶ 120, is baseless, conclusory and patently insufficient to state any claim that relies on Stark Law violations.

Third, Relator's claims based on alleged violations of the Antikickback Statute, 42 U.S.C. § 13210a-7b (the "**AKS**") should be dismissed as a matter of law because they also are insufficiently pled. To sufficiently plead a kickback scheme, Relator is required to allege specific facts and details regarding, for example, who paid or received the alleged kickbacks, the specific roles played by the alleged participants in the alleged scheme and the false claims allegedly submitted. *See U.S. ex rel. Mooney v. Americare, Inc.*, No. 06-CV-1806 FB VVP, 2013 WL 1346022, at *4 (E.D.N.Y. Apr. 3, 2013). The TAC is devoid of these requisite facts and details. Indeed, the TAC's allegations of "financial inducements to physicians", which rely in part on allegations made on information and belief, are speculative and conclusory. *See* TAC ¶¶ 96-98. Likewise, other than listing names of nursing homes that allegedly received "discounts", the

Nursing Home Discount Allegations lack the necessary detail and concrete facts required to survive dismissal. *See* TAC ¶¶ 99-118. Because Relator’s conclusory and speculative allegations regarding the alleged kickback scheme by the collective “Defendants” fall woefully short of sufficiently stating a claim against Defendants based on AKS violations, such claims cannot survive dismissal. *See Mooney*, 2013 WL 1346022, at *4.

Fourth, the FCA, the NYFCA and the NJFCA all impose liability for, *inter alia*, “knowingly” presenting or causing to be presented, a false or fraudulent claim “for payment or approval.” 31 U.S.C. § 3729(a); N.Y. Fin. Law § 189(a); N.J. Stat. § 2A:32C-3. Thus, to adequately plead the scienter element of its fraud claims, Relator was required to “plead the factual basis which gives rise to a strong inference of fraudulent intent” **as to each defendant**. *United States v. Strock*, 982 F.3d 51, 66 (2d Cir. 2020) (citation omitted); *DeAngelis v. Corzine*, 17 F. Supp. 3d 270, 281–82 (S.D.N.Y. 2014) (“In a case involving multiple defendants, plaintiffs must plead circumstances providing a factual basis for scienter for each defendant; guilt by association is impermissible.”). The TAC fails in this regard. The TAC’s allegations of scienter are bareboned, conclusory and fail to include any facts specific to BIM or Shiel Lab. *See, e.g.*, TAC ¶¶ 5, 119-20, 128-29, 131, 146, 158. Thus, dismissal is required.

Fifth, because Counts I, II, IV and V of the TAC fail to sufficiently allege any traditional false claim, the TAC’s “reverse” false claims in Counts III-V necessarily fail. Significantly, the viability of a “reverse” false claim relies on whether a relator has plausibly alleged that the defendants caused the submission of false claims in the first instance. *See U.S. ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, 551 F. Supp. 3d 27, 47–48 (E.D.N.Y. 2021) (citing cases and dismissing reverse false claim where relator failed to allege a regular false claim), *aff’d*, No. 21-2117, 2022 WL 17818587 (2d Cir. Dec. 20, 2022). Where a relator fails to sufficiently allege a traditional false claim, “it cannot have alleged an obligation to pay [or refund] money to

the government,” thus making it impossible to sufficiently plead the necessary elements of a “reverse” false claim. *Id.* Accordingly, because the TAC’s traditional false claims must be dismissed for failure to state a claim, its “reverse” false claims also must be dismissed. *See id.*

Sixth, the TAC’s “reverse” false claims in Counts III-V further fail because “a reverse false claim cannot turn on the same conduct underlying a traditional false claim[]” or “mirror” a relator’s traditional false claim. *U.S. ex rel. Foreman v. AECOM*, 19 F.4th 85, 119 (2d Cir. 2021); *see also id.* (“Because Foreman’s reverse false claims mirror his false claims under § 3729(a)(1)(A) and 3729(a)(1)(B), he fails to state plausible claims.”). Here, the conclusorily alleged “overpayments” allegedly resulted from the same purported fraud underlying the claims in Counts I–II. For this additional reason, the TAC’s “reverse” false claims must be dismissed.

VI. THIS COURT SHOULD DISMISS COUNTS VI AND VII AS AGAINST BIM MEDICAL INC. AND “SHIEL MEDICAL LABORATORY” UNDER FED. R. CIV. P. 12(b)(1) AND FED. R. CIV. P. 12(b)(6).⁷

Counts VI and VII should be dismissed because Relator – a corporation – lacks standing to bring Federal and State employment retaliation claims on behalf of non-party “John Doe”. “The Art. III judicial power exists only to redress or otherwise to protect against injury *to the complaining party*.” *Vermont Agency*, 529 U.S. at 771–72 (citation omitted) (emphasis in original). “An interest unrelated to injury in fact is insufficient to give a plaintiff standing[.]” *Id.* at 772–74. Neither the FCA nor the NJ CEPA includes an exception to the constitutional standing requirements that would allow a corporate relator to stand in the shoes of an anonymous individual for purposes of bringing that individual’s statutory employment retaliation claims. *See* 31 U.S.C. § 3730(h) (regarding Count VI); N.J.S.A. 34:19–1, *et seq.* (regarding Count VII). Thus, Relator’s attempt to bring Doe’s retaliation claims in Counts VI and VII must fail as a matter of law, and

⁷ Although Counts VI and VII do not appear to be against BIM or Shiel Lab, Defendants nevertheless raise this argument out of an abundance of caution.

this Court should dismiss Counts VI and VII for lack of subject matter jurisdiction pursuant to Rule 12(b)(1). See *Vermont Agency*, 529 U.S. at 771–72, *supra*; *Conn. Parents Union v. Russell-Tucker*, 8 F.4th 167, 172 (2d Cir. 2021) (“A district court properly dismisses an action under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction if the court lacks the statutory or constitutional power to adjudicate it, such as when the plaintiff lacks constitutional standing to bring the action.” (internal citations and quotation marks omitted)).

Additionally, to be liable under 31 U.S.C. § 3730(h) and NJ CEPA for retaliation, a person must be the **employer** of the employee allegedly being retaliated against. See *U.S. ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 95 (2d Cir. 2017) (discussing liability under 31 U.S.C. § 3730(h)); *D’Annunzio v. Prudential Ins. Co. of Am.*, 927 A.2d 113, 119 (N.J. 2007) (discussing liability under NJ CEPA). Assuming *arguendo* that Relator has standing to bring John Doe’s retaliation claims in the first instance (which Relator does not), the TAC still has not, and cannot, sufficiently plead retaliation claims against BIM (or Shiel Lab) for the simple reason that the TAC admits that at the time of the alleged retaliatory termination, the anonymous “John Doe” was employed by Spectra Holdco, LLC (which Relator alleges “is owned and controlled by Fresenius”), not BIM (or Shiel Lab). See TAC ¶¶ 2, 166-167. Thus, Counts VI and VII should be also dismissed as against BIM (and Shiel Lab) pursuant to Rule 12(b)6.

VII. THE COURT SHOULD DENY ANY REQUEST FOR LEAVE TO AMEND.

Given all of its deficiencies, including, but not limited to the reasons set forth herein, dismissal of the TAC in its entirety with prejudice is appropriate and any request for leave to amend should be denied. **First**, the TAC is Relator’s **fourth bite at the apple** for a lawsuit that began in 2016 and was investigated by the States of New Jersey and New York, as well as the United States, all of whom declined to intervene. **Second**, Relator has had ample time and several opportunities to file sufficiently pled allegations. Nevertheless, Relator has repeatedly failed to do

so. Moreover, before filing the TAC, Relator had the benefit of knowing the SAC's numerous pleading deficiencies, which were set forth in the First Pre-Motion Letters. Despite this knowledge, the TAC failed to correct any of those deficiencies. If Relator could have alleged facts to save its claims from dismissal, surely Relator would have done so in the TAC. Thus, further amendment is undoubtedly futile. **Third**, Relator should not be allowed endless opportunities to amend its allegations in an attempt to sufficiently state claims. Each amendment causes further harm to Defendants. Indeed, BIM, Shiel Lab and others have been expending time and money for seven years responding to investigations, gathering and producing evidence and defending themselves against Relator's still unsupported and insufficient allegations against them. Allowing Relator to further amend its allegations, despite its "repeated failure to cure deficiencies by amendments previously allowed[.]" is unwarranted and unjust. Thus, any request by Relator for leave to amend should be denied. *See U.S. ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 28 (2d Cir. 2016) ("Leave to amend should be freely give[n] ... when justice so requires, but should generally be denied in instances of futility, undue delay, bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, or undue prejudice to the non-moving party[.]" (citations and internal quotation marks omitted)).

CONCLUSION

At its core, the TAC suffers from multiple fatal deficiencies and cannot stand as a matter of law. Allowing Relator a **fifth** bite at the apple to file a Fourth Amended Complaint would be futile, unwarranted and unjust. Accordingly, the TAC should be dismissed with prejudice.

Dated: October 30, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY on this 30th day of October, 2023 that a copy of the foregoing Memorandum of Law in Support of Defendants Shiel Medical Laboratory and BIM Medical Inc.'s Motion to Dismiss Third Amended Complaint was served on the following counsel via email, pursuant to Rule V.B.1 of the Individual Rules of Judge Nicholas G. Garaufis and in accordance with the Court's Order entered September 14, 2023:

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